UNITED STATES DISTRICT COURT FOR THE SOUTHERN DISTRICT OF NEW YORK

In re ASTRAZENECA PLC SECURITIES LITIGATION	Case No.: 1:21-cv-00722-JPO

DEFENDANTS' REPLY MEMORANDUM OF LAW IN FURTHER SUPPORT OF THEIR MOTION TO DISMISS THE AMENDED COMPLAINT

FRESHFIELDS BRUCKHAUS DERINGER US LLP
Meredith Kotler
Mary Eaton
Shannon K. McGovern
Adam M. Rosenfeld
601 Lexington Avenue, 31st Floor
New York, NY 10022
Tel. (212) 277-4000

Attorneys for Defendants

February 4, 2022

TABLE OF CONTENTS

Page

TABLE OF AUTHORITIES

Page

Cases

Rules

TABLE OF ABBREVIATIONS

¶	Paragraphs of the AC
AC	Amended Complaint for Violations of the Federal Securities Laws, filed July 12, 2021 (ECF No. 42)
Alexion	Alexion Pharmaceuticals, Inc.
Annex B	Annex B to Mov., filed Sept. 27, 2021 (ECF No. 46-2)
Annex C	Annex C to this Reply Memorandum of Law, summarizing Defects in Statements Challenged in the AC, as identified in Defendants' Briefing
Annex D	Annex D to this Reply Memorandum of Law, identifying Post-Class Period Exhibits Challenged in Opposition
AZ	Defendant AstraZeneca plc
AZD1222	A recombinant adenovirus COVID-19 vaccine developed by Oxford and AZ, previously known as "ChAdOx1 nCoV-19," subsequently referred to as "COVID-19 Vaccine AstraZeneca," and now known as "Vaxzevria"
CFO	Chief Financial Officer
CHMP	EMA's Committee for Medicinal Products for Human Use
COV001	Oxford-led Phase I/II clinical trial in the UK for AZD1222
COV002	Oxford-led Phase II/III clinical trial in the UK for AZD1222
COV003	Oxford-led Phase III clinical trial in Brazil for AZD1222
COVID-19	Coronavirus disease 2019, an infectious disease caused by the SARS-CoV-2 virus
CP	Putative Class Period, June 15, 2020 through January 29, 2021, inclusive, as defined in ¶ 1
CW	Confidential Witness
Defendants	AZ, Mr. Soriot, Mr. Dunoyer, and Dr. Pangalos
Dr. Pangalos	Defendant Dr. Menelas Pangalos
DSM	Data and Safety Monitoring
DSMB	Data and Safety Monitoring Board
EU	European Union

EMA	European Medicines Agency
EUA	Emergency Use Authorization
Ex.	Numbered exhibit to the Declaration of Marques S. Tracy in support of Defendants' Motion to Dismiss, executed Sept. 27, 2021 (ECF No. 47) or lettered exhibit to the Declaration of Murielle J. Steven Walsh in support of Plaintiffs' Opposition, executed Dec. 10, 2021 (ECF No. 52)
Exchange Act	Securities Exchange Act of 1934, 15 U.S.C. § 78a *et seq.*
FDA	US Food and Drug Administration
FLS	Forward-looking statement
Individual Defendants	Mr. Soriot, Mr. Dunoyer, and Dr. Pangalos
LD/SD	Low dose/standard dose regimen used in COV002
Mov.	Defendants' Memorandum of Law in Support of Their Motion to Dismiss, filed Sept. 27, 2021 (ECF No. 46)
Mr. Dunoyer	Defendant Marc Dunoyer
Mr. Soriot	Defendant Pascal Soriot
Opposition or Opp.	Plaintiffs' Memorandum of Law in Opposition to Defendants' Motion to Dismiss, filed Dec. 10, 2021 (ECF No. 51)
Oxford	University of Oxford, including the Jenner Institute and the Oxford Vaccine Group
Plaintiffs	Lead Plaintiffs Nuggehalli Balmukund Nandkumar and Wayne County Employees' Retirement System, and Plaintiff Vladimir Zhukov
Professor Pollard	Professor Sir Andrew J. Pollard, Director of Oxford Vaccine Group
PSLRA	Private Securities Litigation Reform Act of 1995, 15 U.S.C. § 78u-4 *et seq.*
Rule 9(b)	Federal Rule of Civil Procedure 9(b)
SD/SD	Standard dose/standard dose regimen used in COV002
Section 10(b)	Section 10(b) of the Exchange Act
Section 20(a)	Section 20(a) of the Exchange Act

PRELIMINARY STATEMENT

The Opposition confirms that the AC alleges no fraud, let alone with the particularity required by the PSLRA. Abandoning many of the statements and most of the alleged omissions challenged in the AC, Plaintiffs seize upon the non-disclosure of certain details regarding ex-US clinical trials for AZD1222: (i) in the UK COV002 trial, a "manufacturing error" for one batch of doses led to the use of a second dosing regimen, and a related protocol amendment to keep those who received this regimen in the trial; and (ii) in COV002 and the Brazil COV003 trial, AZ allegedly failed to test an undefined "sufficient" number of participants aged 55+. As to the first, AZ disclosed up front that the vaccine would be tested "at various doses"; the AC alleges no facts indicating that anyone at AZ believed, or should have believed, that use of the second dosing regimen reflected some underlying problem with COV002 or the vaccine; and ultimately both regimens produced a safe, efficacious vaccine. As to the second, AZ never guaranteed or even suggested any particular number of 55+ participants in the ex-US trials, and instead disclosed that the number of such participants was limited. More fundamentally, multiple regulators approved the vaccine's use, including for those aged 55+, and it is so used around the globe, saving countless lives. Try as they might, Plaintiffs cannot avoid these judicially noticeable, undisputed matters integral to the AC and of which all investors had notice.

Not surprisingly, the Opposition cites no authority sustaining at the pleading stage securities fraud claims concerning statements about clinical trials when the therapy being tested *receives approval and is in use*. Nor can Plaintiffs distinguish the extensive authority cited by Defendants holding that criticisms of clinical trial design, as here, do not plead securities fraud. The alleged omissions—detailing the genesis behind using a second dosing regimen in COV002, and that Defendants did not share Plaintiffs' view regarding the supposed insufficiency of 55+ participants in COV002 and COV003—did not render any challenged statement false, much less knowingly so.

The Opposition fails to identify any actionable misrepresentation or omission, any facts

pleaded with particularity giving rise to the requisite "strong inference" of scienter, and any facts pleading loss causation. The AC should be dismissed on any or all of these grounds. *See* Annex C.

REPLY BACKGROUND

The Opposition expressly acknowledges, or fails to dispute and thus concedes:

- AZD1222 was developed, manufactured, and distributed under the "unprecedented" conditions of a worldwide pandemic and in record time. Opp. 2-3; Mov. 13-14, 31.
- AZ, whose primary therapy areas did not include vaccines, partnered with world-leading vaccinology experts at Oxford, Opp. 3, and Oxford issued its own similar disclosures throughout the Class Period, Mov. 4, 6, 10, 31; Exs. 2, 3, 5, 7, 10, 13, 21, 32, 35, 42, 63.
- AZ and Oxford issued extensive warnings regarding AZD1222, including that the vaccine development effort might fail (although it did not). Opp. 26 & n.25; Mov. 4, 5, 6, 26-27 & Annex B.
- AZ committed to scale up manufacturing pre-approval at its own risk and to sell the vaccine at no profit during the pandemic, and emphasized fair and equitable vaccine distribution, including to developing countries. Opp. 3 & n.5; Mov. 4, 25.[1]
- AZD1222 was approved for use in many countries, both during the CP and after, and without age cutoff for those 55+. Opp. nn.20, 37; Mov. 13, 31 & n.36. Plaintiffs acknowledge some approvals, ¶¶ 115, 120, but improperly ask the Court to ignore others, *infra* Point III.
- AZD1222 is being used around the world, saving countless lives. Opp. n.20; Mov. 14, 31-32.

The Opposition also scales back from the AC. It abandons any challenge to many of the statements block-quoted in the puzzle-pled AC,[2] and divides the challenged statements into three categories (described *infra* Point I), including those purportedly stating that the ex-US trials would "include participants of different ages and/or older participants," which allegedly "implied that the

[1] The Opposition notes that AZ recently announced a "shift away from a nonprofit approach" starting in 2022, Opp. 4 & n.37; Ex. A, but the cited article observes that AZ will continue to deliver the vaccine at no profit to developing countries.

[2] Plaintiffs attempt to justify the AC's use of lengthy block quotes by explaining that the challenged portions are those highlighted in bolded italics. Opp. n.9. As such, Plaintiffs have abandoned any challenge to the *non-highlighted* statements. Additionally, Plaintiffs nowhere defend the AC's failure to link specific challenged statements to specific purported omissions, instead simply repeating verbatim the same lengthy list of assorted omissions after each challenged statement and failing to clarify "which statements link up with which issues in the laundry list." *In re Alcatel Sec. Litig.*, 382 F. Supp. 2d 513, 534 (S.D.N.Y. 2019). This requires dismissal under Plaintiffs' own authority. Opp. n.9; *Ontario Teachers' Pension Plan Board v. Teva Pharm. Indus.*, 432 F. Supp. 3d 131, 153 (D. Conn. 2019) ("nor is it enough for a plaintiff to assert generic and/or identical allegations after each quotation or section, setting forth the reasons why the statement is allegedly false").

number of older participants was sufficient to be studied." Opp. n.2. Plaintiffs concede that this is solely an omissions case, *id.* 2, and abandon most of the alleged omissions in the laundry list repeated throughout the AC, *e.g.*, ¶¶ 48(a)-(h). Instead, the Opposition argues failure to disclose:

1) in COV002, a "manufacturing error" or "dosing error" by one manufacturing contractor caused one batch of its shots to have lower dosage, leading to the use of two dosing regimens (LD/SD and SD/SD) and to amendment of the study's protocol so that those who received the LD/SD regimen could remain in the trial, *see* ¶¶ 40-42, 81; Ex. 42 at 101; and

2) the LD/SD regimen used in COV002 was not tested on anyone 55+ and COV002 and COV003 purportedly did not include sufficient 55+ participants to measure efficacy for them.

E.g., Opp. 1-2, 4-5, 7, 14, 16, 23, 34-35. Yet Plaintiffs acknowledge AZ's and Oxford's disclosures that the vaccine would be tested "at various doses," ¶¶ 47, 50; Opp. 6 & n.11; that in COV002, both regimens well exceeded the 50% efficacy threshold set by public health authorities (at 90% and 62%), ¶¶ 4, 78; Opp. 8; *see* Mov. 11; and that the SD/SD regimen was approved in the UK and elsewhere without age cutoff and is used globally, ¶¶ 115, 120; Opp. 11-12 & nn.20, 37; *see* Mov. 13-14, 31.

ARGUMENT

POINT I: THE AC FAILS TO PLEAD SECTION 10(b) AND 20(a) CLAIMS

A. The AC Fails to Allege an Actionable Misrepresentation or Omission

1. Plaintiffs' Challenge to Purported Statements About Testing of Participants Aged 55+ Fails

Plaintiffs concoct this group of purported misstatements, Opp. n.2, only by misrepresenting and ignoring what Defendants actually said. Statements (i) announcing the start of COV002 with "10,000 adult volunteers," ¶ 44; Opp. 6; (ii) describing that trials would "measure safety and immune responses in different age ranges," ¶¶ 47, 50; Opp. 6, 17 & n.9; and (iii) noting that "data on different age groups is coming . . . in on a weekly basis," ¶ 54; Opp. 6, 17, gave no guarantee or even indication about the number of 55+ participants in the ex-US trials.[3] To the contrary, AZ and Oxford disclosed

[3] In contrast, for the US trial, AZ disclosed that at least 25% of participants would be 65+. Ex.19; *see* Opp. 3.

early on that COV001 included participants aged 18-55, and that COV002 participants would include "a small number of older adults" over 55 (Phase II) and "a large number of people over the age of 18" (Phase III). Exs. 2-4, 6, 7, 12. As shown through analyst queries, the market understood the limited number of older participants. Mov. n.14. The Opposition has no response.

Plaintiffs fare no better challenging statements that simply repeated interim analysis of immunogenicity and reactogenicity data that previously had been presented at IDWeek by Oxford's Professor Pollard. ¶¶ 70, 72, 76; Opp. 6-7, 17 & n.2; *see* Mov. 8-9. These statements gave no guarantee, or indication, about the number of 55+ participants; they said nothing on the subject. And Plaintiffs nowhere claim that Defendants irrationally interpreted, or misrepresented, what the data showed: stronger immune responses across all age groups and lower reactivity in older adults. Mov. 19 & n.17.

Rather, Plaintiffs insist that these statements falsely "implied" that the number of 55+ subjects was "sufficient" to be studied, when purportedly it was not. Opp. 16, 17, 23 & n.2. Plaintiffs nowhere define what a "sufficient" number is, but regardless, they cannot allege that any "impression" created regarding sufficiency was false, when AZD1222 undisputedly was approved and is used for adults of all ages. At bottom, Defendants were not required to describe their trials pejoratively, or to label participation levels as Plaintiffs desire. *See Dalberth v. Xerox Corp.*, 766 F.3d 172, 186-87 (2d Cir. 2014); *Singh v. Schikan*, 106 F. Supp. 3d 439, 448-49 (S.D.N.Y. 2015).

Nor did the purported omissions on which Plaintiffs now seize—details about the genesis of the LD/SD regimen in COV002, and a related protocol amendment to *keep* its recipients in the study—somehow falsely convey that COV002 was proceeding with "no significant setbacks or unusual issues," Opp. 15, 22, a new theory absent from the AC. Plaintiffs acknowledge AZ's early disclosures that AZD1222 would be tested "at various doses,"[4] and they concede both regimens were

[4] Plaintiffs insist it was "vague," Opp. n.13, but the November 19 *Lancet* article further disclosed the use of two dosing regimens, a related protocol amendment, and that only younger cohorts received the lower dose regimen. Ex. 33 at 1982.

shown to be safe and efficacious. *Supra* 3. Plaintiffs do not, and cannot, explain how the additional information would have conveyed some "significant" or "unusual" problem with COV002 or the vaccine, let alone a fundamental one. Indeed, the AC nowhere alleges *any* facts indicating that *anyone* at AZ (or Oxford) considered the use of a second dosing regimen to reflect some problem with COV002 or the vaccine. And the market expects adjustments in ongoing trials, even under ordinary circumstances which were obviously not present here. Plaintiffs baldly assert that the need to amend the COV002 protocol "may have (and in actuality, did), impact the vaccine's ability to obtain EUA," Opp. 22, but that is false and pure speculation. Any US approval (which has not been sought) would be based on the US trial, which was unimpacted by the "manufacturing error" in COV002 and whose design and execution Plaintiffs do not challenge. And ex-US approvals came.[5]

Plaintiffs' authorities, Opp. 15-16, 22, stand in stark contrast, as each concerned omitted facts pointing to fundamental problems and actual failures. For example, in *Kendall v. Odonate Therapeutics, Inc.*, 2021 WL 3406271, *3, 5 (C.D. Cal. Aug. 4, 2021), plaintiffs alleged failure to disclose a significant safety issue: an unexpectedly high number of patients had withdrawn from defendants' clinical trial after experiencing adverse events, requiring an emergency protocol change to *limit* those negative outcomes. Ultimately, the treatment in *Odonate* was discontinued from clinical development, following negative FDA feedback. *Id.* *3. Here, by contrast, the protocol amendment *kept* recipients of the LD/SD regimen in COV002, with efficacy and safety of that cohort demonstrated. *Supra* 3.[6]

[5] Plaintiffs' cavil that no 55+ participants received the LD/SD regimen, Opp. 5, 35, fails. For safety reasons, younger cohorts were recruited first, with "[a] minimum of 2 weeks of safety and immunogenicity data [being] reviewed by the DSMB before recruitment to each successive age cohort." Ex. 33 at 1982. Once COV002 researchers realized the discrepancy that led to a lower dosage for some shots, they addressed the issue and obtained approval of a protocol change to keep those who received the LD shots in the study. Ex. 42 at 101. And, the SD/SD regimen was approved and is used.

[6] *See also In re Delcath Systems, Inc. Sec. Litig.*, 36 F. Supp. 3d 320, 327, 329, 333 (S.D.N.Y. 2014) (FDA denial of approval for medical device; defendants failed to disclose that side effects in treatment group surpassed those from traditional treatments, and that mortality rate was higher for treatment group than control group); *In re Allergan plc Sec. Litig.*, 2019 WL 4686445, *22-24 (S.D.N.Y. Sept. 20, 2019) (product recalls; sole claim not dismissed concerned defendants' disclosures of "possible" link between company's implants and cancer and that negative reports had been made regarding *different* manufacturer's implants, when non-disclosed data indicated that majority of cancer cases involved *defendants'* implants).

Despite their protests to the contrary, Plaintiffs present nothing more than an inactionable critique of COV002 and COV003 trial design, rooted in their subjective assessment that an undefined greater number of individuals aged 55+ should have been included. But the "characterization" of the number of older patients as not "sufficient" is "only [Plaintiffs'] view," not an undisclosed *fact* that was later revealed to the market (nor could it be, given the approvals received). *Kleinman v. Elan Corp., plc*, 706 F.3d 145, 154 (2d Cir. 2013). Plaintiffs cannot meaningfully distinguish the long line of precedent holding otherwise, Mov. 18, 22-23 & nn.15, 22, by insisting that supposedly omitted information (which was disclosed) somehow rendered false Defendants' fully accurate statements about trial subjects (which it did not), Opp. 15, 18, 20, 23 & nn.10, 24. *See, e.g.*, *Kleinman*, 706 F.3d at 154 (no duty to disclose additional details about dose response and form of statistical analysis where defendants never "discussed whether there was a dose response or whether one was expected" and "stated that a post-hoc analysis was used without specifying the methodology").

2. Plaintiffs' Challenge to Statements About Trial Progress and Data Fails

The Opposition notes Defendants' disclosure that Phase II/III trials had "launched" or were "ongoing" in the UK, Brazil, and South Africa, Opp. 6 & n.2; ¶¶ 44, 49-51, 57, and insists that "[o]nce [Defendants] spoke about the status of that trial, they had a duty to disclose" the "manufacturing error" leading to a second dosing regimen in COV002 and related protocol amendment to keep its recipients in the trial, Opp. 14 & n.11. Not so. There is no generalized duty to disclose "negative facts," Mov. 17, or "any and all material information," or even all facts investors "would very much like to know," *City of Riviera Beach Gen. Emp. Ret. Sys. v. Macquarie Infrastructure Corp.*, 2021 WL 4084572, *6 (S.D.N.Y. Sept. 7, 2021) ("there is no boundless duty to reveal all facts on the subject just because a company or its officers speak on a subject"). Nor is there some duty to disclose every development or protocol amendment in an ongoing clinical trial. Mov. 17, 22-23 & n.22. To survive dismissal, Plaintiffs must allege, with particularity, that the omitted detail about use of the LD/SD regimen in

COV002 and related protocol amendment rendered false these limited statements about trials "launch[ing]" or "ongoing." Plaintiffs do not and cannot do this.

The same goes for Defendants' generalized descriptions of trial progress—AZ had "advanced its ongoing response to address COVID-19," "[t]he study remains on track," and clinical development "is progressing globally"—and Mr. Soriot's expression of "confidence in the design of the trials, safety protocols and DSM." Opp. 6, 18, 21-22 & n.2; ¶¶ 50, 52, 57, 67, 75. Again, Plaintiffs do not and cannot allege how the same purported omissions rendered these statements false, particularly given prior disclosures about testing at "various doses" and the limited number of 55+ subjects, the absence of any facts alleging that anyone at AZ believed the "manufacturing error" reflected some problem with COV002 or the vaccine, and that both dosing regimens demonstrated efficacy. *Supra* 3, 4-5.[7]

Moreover, these latter statements regarding trial progress, and others like them, are too generalized to be relied upon and thus are inactionable puffery. Mov. 25 & n.24. Contrary to Plaintiffs' assertion, Opp. 22, this puffery did not somehow become actionable simply because it was expressed several times. Plaintiffs' attempt to distinguish the many cases Defendants cited, Opp. n.21, fails, as those cases ruled that virtually identical generalized statements were inactionable.

Finally, these statements of trial progress, and Defendants' interpretation of clinical trial data, *supra* 4; ¶¶ 52, 70, 72, 76, are inactionable opinions under *Omnicare, Inc. v. Laborers District Council Construction Industry Pension Fund*, 575 U.S. 175 (2015). Plaintiffs assert liability only under *Omnicare*'s third prong, again complaining that the genesis behind the LD/SD dosing regimen and related protocol amendment were omitted. Opp. 23. Just as this omitted detail did not render any statement false, it did not conflict with what a reasonable investor would take from Defendants' disclosed opinions. 575 U.S. at 189; *see also Tongue v. Sanofi*, 816 F.3d 199, 213 (2d Cir. 2016) (no opinion liability

[7] Mr. Soriot's "incredibly promising" statement, Opp. n.2; ¶ 74, addressed a *different* COVID treatment, Mov. n.23.

where plaintiffs failed "to show a relationship between the [omitted facts] and Defendants' statements touting the results of [clinical] trials"). Contrary to Plaintiffs' assertion, Opp. 24, Defendants' opinions are not actionable because the FDA has not evaluated AZD1222 or because some commentators have criticized it. As in *In re Philip Morris International Inc. Securities Litigation*, 2021 WL 4135059 (S.D.N.Y. Sept. 10, 2021), Opp. 24, which Plaintiffs fail to distinguish, the facts demonstrating the reasonableness of Defendants' opinions, including that both COV002 dosing regimens demonstrated efficacy and the many approvals that came, are pleaded in the AC, *e.g.*, ¶¶ 78, 93, 115, 120.[8]

3. Plaintiffs' Challenge to AZ's Science and Safety Commitments Fails

Nor can Plaintiffs base liability on statements concerning AZ's "adherence to highest scientific and clinical standards," "commitment to the highest safety standards," and "confidence in the design of the trials, safety protocols and DSM," or a related pledge by Mr. Soriot. Opp. 7-8 & n.2; ¶¶ 60-61, 63, 67, 73. These general statements did not "put AZN's conduct of the trials at issue," Opp. 19, or trigger some duty to disclose every detail about the ex-US trials, *supra* 6-7.[9] Plaintiffs cannot explain how any omission of detail regarding the LD/SD regimen rendered false AZ's commitments.[10]

Moreover, the commitments are too generalized for investors to rely on, rendering them inactionable. Mov. 21 & n.19. Plaintiffs' assertion that COVID vaccine development is "critically important," Opp. n.15, is beside the point; the statements are inactionable because they are "broad, general statements," not because they relate to unimportant subject matter. *ECA, Local 134 IBEW*

[8] Plaintiffs' reliance on *In re iDreamSky Technology Limited Securities Litigation*, 236 F. Supp. 3d 824, 833-34 (S.D.N.Y. 2017), Opp. 23, is unavailing. Defendants there predicted a game launch in 2014 but, according to CWs, allegedly knew when disclosing their projections that the launch would be delayed beyond that date. Plaintiffs plead nothing similar.

[9] In *Meyer v. Jinkosolar Holdings Co.*, 761 F.3d 245, 250-51 (2d Cir. 2014), Opp. 19, in contrast, a prospectus described a company's pollution abatement equipment and monitoring but omitted that they "were then failing to prevent substantial violations." *Id.* The Court noted that the failure to disclose "then-ongoing and serious pollution violations" could be found "to be an omission that renders misleading the comforting statements in the prospectus about compliance." *Id.* Again, Plaintiffs point to no similar problem. *Supra* 4-5.

[10] With regard to the safety commitments only, Plaintiffs repeat their full laundry list of alleged omissions from the AC. Opp. 18-19. But Plaintiffs do not even attempt to respond to Defendants' many arguments about those other purported omissions, Mov. 23-25, thus conceding Defendants' points.

Joint Pension Trust of Chicago v. JP Morgan Chase Co., 553 F.3d 187, 206 (2d Cir. 2009). Nor can Plaintiffs distinguish the many cases Defendants cited on the basis that codes of conduct and commitments to good corporate governance are somehow less important, or that the federal securities laws apply differently in the context of a "dramatically expedited timeline" for corporate action. Opp. n.15.[11]

4. Many Challenged Statements Are Protected by the PSLRA's Safe Harbor

With the exception of statements that trials had launched or moved forward and AZ's commitment to science and safety, Defendants' statements are forward-looking: they discuss what the trials would test and what the data would show. Mov. 26; *see, e.g.*, ¶¶ 54, 76. Indeed, on November 23, 2020, *after* the last challenged statement, ¶ 77, AZ noted that "[m]ore data will continue to accumulate and additional analysis will be conducted," Ex. 34. Plaintiffs complain about the supposed omission of purportedly "then-current facts" (the "manufacturing error" and Plaintiffs' view of insufficient 55+ participants), Opp. 26 & n.23, but the salient question is whether *the disclosures* are forward-looking, which they are.

The Opposition's own narrowed omissions theory confirms this. Plaintiffs cannot point to any statement that there were or would be no protocol amendments, or that a particular number of 55+ participants had been or would be tested in the ex-US trials. Rather, Plaintiffs' theory is that, by not immediately disclosing further detail about the use of LD/SD in COV002, AZ somehow hid that its trial design *would be* unreliable and insufficient for approval—a prediction later proved wrong.

Plaintiffs' assertion that the challenged statements are material, Opp. 26, is irrelevant. Statements are protected if they satisfy *any* of the three statutory safe harbors. *See Slayton v. American Express Co.*, 604 F.3d 758, 766 (2d Cir. 2010); *In re Adient plc Sec. Litig.*, 2020 WL 1644018, *18

[11] The Opposition repeats the AC's allegation that Mr. Soriot's September 8 pledge promised that "AZN would submit its vaccine for approval only after a single Phase III study." Opp. 8 & n.2. That is not what the pledge said, *see* ¶ 63, nor would it have been reasonably understood that way. Well before September 8, AZ and Oxford repeatedly described that Phase III trials would be conducted in multiple jurisdictions. *See* ¶¶ 47, 49-54, 57.

(S.D.N.Y. Apr. 2, 2020). Here, Defendants raise two: (i) FLS accompanied by adequate cautionary language; and (ii) actual knowledge of falsity not alleged. Mov. 26-27. Both apply because (i) the Opposition mounts no non-conclusory challenge to the thorough cautionary language disclosed by AZ and Oxford throughout (with the single example Plaintiffs cherry pick, Opp. n.25, just one of many, Annex B),[12] and (ii) Plaintiffs do not allege actual knowledge of falsity, *infra* 12.

B. The AC Fails to Plead the Requisite Strong Inference of Scienter

1. No Motive

The Opposition identifies no cognizable motive pleaded in the AC. Plaintiffs concede the absence of stock sales by any Individual Defendant, and wrongly insist that is a "neutral factor." Opp. 33.[13] Numerous cases hold that such absence undermines any inference of scienter. Mov. 28 & n.27; *In re Gildan Activewear, Inc. Sec. Litig.*, 636 F. Supp. 2d 261, 271-72 (S.D.N.Y. 2009).[14]

The proffered motive to obtain prestige and avoid reputational or financial harm, Opp. 32, is nothing more than a repackaged generic motive to appear profitable and successful, routinely rejected. Mov. 28 & n.28. The Opposition has no response and fails to address the cases Defendants cited.[15]

As for the proffered motive to fund AZ's acquisition of Alexion, Plaintiffs make no attempt to meet the test articulated in *ECA*, Mov. 28-29, nor could they. Two of three cases Plaintiffs cite are out-of-circuit. Opp. 32. The third, *In re Vivendi Universal, S.A. Securities Litigation*, 381 F. Supp. 2d 158 (S.D.N.Y. 2003), predates *ECA* and is distinguishable because plaintiffs alleged that the acquisition

[12] Plaintiffs' authority, Opp. 27, involved cautionary language that noted certain risks were merely possible without revealing such risks had materialized. Plaintiffs fail to identify what risk materialized here, as AZD1222 was approved.

[13] Mr. Soriot's gift of shares to family, Opp. n.34, neither was a sale nor resulted in pecuniary gain to him.

[14] *In re Reserve Fund Securities and Derivative Litigation*, 732 F. Supp. 2d 310, 320 n.6. (S.D.N.Y. 2010), Opp. 33, did not disagree with this well-observed principle, but found that a different motive had been adequately alleged.

[15] Plaintiffs repeat that the "microscope that AZN was under regarding the creation of AZD1222" motivated Defendants to conceal purported failures of the ex-US clinical trials. Opp. n.31. That is implausible, as clinical trial results would be assessed by regulators, publicly. That AZ would jeopardize its reputation with regulators and the public—for a vaccine outside its core therapy areas, to be distributed at no profit during the pandemic—defies logic. *See Gillis v. QRX Pharma Ltd.*, 197 F. Supp. 3d 557, 600 (S.D.N.Y. 2016).

"would not otherwise be possible" without an inflated stock price—something Plaintiffs cannot allege.

2. No Conscious Misbehavior or Recklessness

Nor does the Opposition identify the "correspondingly greater" circumstantial allegations of conscious misbehavior or recklessness that must alleged here, in the absence of motive. Mov. 29.

Plaintiffs' scienter argument rests solely on the assertion that Defendants had "awareness of the dosing error" that led to use of the LD/SD dosing regimen and related protocol amendment in COV002, identifying no other supposedly contradictory information. Opp. 28-31. For all the reasons that error did not contradict or render false any challenged statement, *see supra* Point I.A.1-3; Mov. 17-23, purported awareness of the error cannot plead Defendants' knowing or reckless making of false statements. *See Shields v. Citytrust Bancorp, Inc.*, 25 F.3d 1124, 1129 (2d Cir. 1994) (plaintiffs failed to allege that disclosures were "inconsistent with current data"); *In re HEXO Corp. Sec. Litig.*, 524 F. Supp. 3d 283, 313 (S.D.N.Y. 2021). While Plaintiffs insist that one contractor's error for a batch of its doses was "so serious," Opp. 29, they fail to allege *any fact* indicating that *anyone* at AZ believed, or should have believed, that using a second dose regimen reflected some problem with COV002 or the vaccine. To the contrary, undisputedly, the protocol amendment *kept* recipients of the LD/SD regimen in the trial, regulators were transparently notified, and the regimen demonstrated efficacy. *Supra* 3.[16]

Construction Industry & Laborers Joint Pension Trust v. Carbonite, Inc., 22 F.4th 1 (1st Cir. 2021), ECF No. 53, does not change the result. There (unlike here), plaintiffs pointed to several alleged facts contradicting defendants' touting of their software product that was later withdrawn from market: internal employee reports that the product was not ready for launch; trial runs were uniformly unsuccessful; and the creation of a "tiger team" focused on fixing the product after its launch,

[16] For the same reason, the fact that "other" unnamed AZ employees "communicated with the regulator about the protocol change," Opp. 28, 33, does not plead AZ's corporate scienter through purported knowledge of any *contradictory* facts.

including putting out a "large patch" and "hundreds of bug fixes." *Id.* 4, 9-10.[17]

Even putting aside Plaintiffs' failure to allege that the "manufacturing error" in Oxford-led COV002 was *contradictory* information, Plaintiffs do not allege that the Individual Defendants had actual knowledge of it. *See* Opp. 28.[18] Plaintiffs instead argue that the Individual Defendants must have known because they had "access to" information about it, Opp. 28-29, but nowhere specify the reports or sources of such information, as they must, Mov. 29. Plaintiffs also insist that the Individual Defendants must have known because regulators were notified, Opp. 29, but allege no facts indicating that any Individual Defendant participated in the notification process, merely proffering their conclusion that the issue was "so serious," *supra* 11.[19] Nor must Mr. Soriot or Dr. Pangalos have known simply because they spoke about trial progress and "the inclusion of 55+ subjects," Opp. 29, given the limited nature of their statements and the "manufacturing error," *supra* 3, 4-7.

Plaintiffs also speculate that the Individual Defendants must have known about the error because of their "corporate positions and active involvement in overseeing and publicly communicating the development of AZD1222." Opp. 30. Such generic assertions are insufficient, Mov. n.29; *Gildan*, 636 F. Supp. 2d at 273, particularly without any facts showing that use of a second regimen was considered within AZ (or Oxford) to reflect a problem with COV002 or the vaccine.

While disavowing reliance on the core operations doctrine, Plaintiffs argue that the Individual Defendants must have been aware of every detail in the ex-US trials given the "importance of the

[17] The Opposition's authority, Opp. 28-31, similarly consists of plaintiffs alleging defendants' access to undisclosed information *contradicting* public disclosures. *See, e.g.*, *New Orleans Emp. Ret. Sys. v. Celestica, Inc.*, 455 F. App'x 10, 13-14 (2d Cir. 2011) (rising inventory levels); *In re Mylan N.V. Sec. Litig.*, 2018 WL 1595985, *12 (S.D.N.Y. Mar. 28, 2018) (alleged illegal conduct); *SEB Inv. Mgmt. AB v. Endo Int'l PLC*, 351 F. Supp. 3d 874, 906 (E.D. Pa. 2018) (adverse safety data); *In re PTC Therapeutics, Inc. Sec. Litig.*, 2017 WL 3705801, *16 (D.N.J. Aug. 28, 2017) (trials did not meet primary endpoints).

[18] Whether the error is termed a "manufacturing error," "dosing error," or "difference in manufacturing technique" does not create a fact issue precluding dismissal. Opp. n.11. The salient point is that the LD/SD recipients were kept in COV002, and the AC pleads no facts suggesting that anyone at AZ (or Oxford) believed that its use reflected some problem with COV002 or the vaccine. And, both dosing regimens demonstrated safety and efficacy.

[19] Plaintiffs identify a letter that went to trial participants about the error, but admit it was sent by Oxford. Opp. n.27.

vaccine" and the "unique" circumstance of COVID. Opp. 30 & n.30. That is nothing more than a repackaging of the core operations doctrine, with the concession that Plaintiffs cannot meet its requirements. Mov. 31. Regardless, such inferences do not independently establish scienter. *Id.*

Finally, the Opposition relegates the requisite balancing of competing inferences to a footnote, Opp. n.37, raising no compelling inference of fraud. Plaintiffs repeat their conclusory assertion that Defendants "knowingly or recklessly" omitted information, *id.*, but nowhere dispute the facts Defendants identify that raise the far more compelling inference of non-fraudulent intent, Mov. 31-32. Plaintiffs attempt to detract from some of these by noting that the FDA has not passed on AZD1222, government funding defrayed certain costs, and AZ intended to make a profit from the vaccine at some undefined future time. Opp. n.37. That effort easily fails. *See Tongue*, 816 F.3d at 213 (undisclosed negative feedback from FDA did not render false statements touting clinical trial results where global pharmaceutical had obtained approval from EU and other countries). Similarly, Plaintiffs insist that certain analysts, commentators, and others criticized the AZD1222 trials or had more "confidence" in other COVID-19 vaccines. Opp. nn.20, 37. But that is irrelevant to Defendants' intent, and those very critics acknowledged AZD1222's efficacy, safety, and value to global vaccination efforts, Mov. 11-12 & n.9; *see also* ¶ 32 (identifying benefits of AZD1222). Nothing to which Plaintiffs point suggests that Defendants engaged in fraud or refutes that AZ stepped up to help ensure the fair, equitable distribution of a COVID-19 vaccine during a worldwide pandemic, at no profit.

C. The AC Fails to Plead Loss Causation

The Opposition merely repeats that stock drops followed certain disclosures without explaining how those disclosures allegedly *caused* Plaintiffs' losses, as required. *See Dura Pharms., Inc. v. Broudo*, 544 U.S. 336, 345 (2005) (securities laws do not "provide investors with broad insurance against market losses," but protect against "economic losses that misrepresentations actually cause").

November 23 and 24, 2020 Disclosures. Plaintiffs insist that a stock drop followed AZ's

November 23 and 24 disclosures providing detail about the LD/SD regimen in COV002. Opp. 34-35. Plaintiffs thus abandon any reliance on press and commentator reaction, *see* ¶¶ 83-84, 86-88, 90, 92, which did not plead loss causation in any event, Mov. 32-33. Regardless, while Plaintiffs insist that the additional detail from AZ was new—despite AZ's prior disclosures, *supra* 3-4 & n.4—Plaintiffs do not and cannot claim that it revealed or corrected any prior *misrepresentation*, Mov. 33; *supra* Point I.A.

December 14, 2020 Disclosure. Plaintiffs repeat that a stock drop followed Dr. Pangalos' statement, made with the benefit of hindsight, that AZ would have done things "a little bit differently" had it designed COV002. Opp. 35. Plaintiffs do not even attempt to explain this as a corrective disclosure. Plaintiffs instead reference the theory of materialization of risk, *id.*, but that is nowhere alleged in the AC. Regardless, Plaintiffs make no attempt to explain what risk was hidden or how Pangalos' statement revealed it.[20] Plaintiffs also cannot avoid their failure to disaggregate the alleged effects of Dr. Pangalos' statement from the contemporaneous disclosure of the Alexion merger. Mov. 33. Plaintiffs insist that disaggregation is "fact-intensive," Opp. 35, but fail even to *acknowledge* the simultaneous announcement. Neither *Allergan* nor *Delcath*, Opp. 36, involved a stock drop coinciding with several disclosures of unrelated events, Mov. 33 & n.35; *see also Lattanzio v. Deloitte & Touche LLP*, 476 F.3d 147, 157-58 (2d Cir. 2007) (affirming dismissal for failure to disaggregate).

January 2021 Disclosures. Plaintiffs further observe that a stock drop followed disclosures that German government "sources" and other "news" questioned the effectiveness of AZD1222 for those 65+ and/or predicted that regulatory approval might not come. Opp. 35. Again, Plaintiffs abandon any theory that such speculation and commentary were corrective disclosures—they were not, Mov. 34—and instead pursue a new materialization of risk theory, Opp. 35. Plaintiffs concede that the "sources" were immediately discredited by the German government, ¶ 119, and that the

[20] In *Mylan*, 2018 WL 1595985, *18, Opp. 35, in contrast, plaintiffs alleged undisclosed illegal conduct that was later revealed upon announcements of a regulatory notification of misclassification and DOJ criminal investigation.

CHMP—at the very same time—*approved* use of the vaccine, without age cutoff, ¶ 120. As a matter of law, no previously hidden risk materialized in January 2021.[21]

POINT II: THE CLAIMS AGAINST MR. DUNOYER SUFFER FURTHER DEFECTS

First, conceding that Mr. Dunoyer neither made nor signed any challenged statement, Plaintiffs argue that he was the "maker" of certain challenged statements for Section 10(b) liability under the group pleading doctrine. Opp. 36 & n.38. Even leaving aside the open question whether that doctrine survived *Janus Capital Group v. First Derivative Traders*, 564 U.S. 135 (2011), *see In re Banco Bradesco S.A. Sec. Litig.*, 277 F. Supp. 3d 600, 638-41 & n.7 (S.D.N.Y. 2017), it applies only to collectively-authored written documents, and not to oral statements or to statements expressly attributed to others, *see Das v. Rio Tinto PLC*, 332 F. Supp. 3d 786, 808-809 (S.D.N.Y. 2018).

Further, the doctrine does not apply in the absence of non-conclusory allegations detailing Mr. Dunoyer's "role in the creation, formulation, or dissemination of" group-published statements. *See In re Braskem S.A. Sec. Litig.*, 246 F. Supp. 3d 731, 762 (S.D.N.Y. 2017). The AC's sole references to Mr. Dunoyer concern his participation on conference calls, ¶¶ 51, 74, which Plaintiffs concede were not group-published, *see* Opp. n.38. The AC's conclusory allegations that all Individual Defendants were "hands-on managers" who "had direct involvement in and responsibility over the day-to-day operations of the Company," ¶¶ 18, 158, fail to explain whether and how Mr. Dunoyer—AZ's CFO—was involved in and responsible for disclosures regarding vaccine development, *see Braskem*, 246 F. Supp. 3d at 762 ("global and general" allegations that officer "had direct involvement in the day-to-day operations" of company, was provided with copies of purportedly misleading statements, and "had the ability to prevent" their dissemination insufficient).[22]

---

[21] Without a Section 10(b) violation, *supra* Point I.A-C, there can be no Section 20 claim, Opp. n.40; Mov. 34.

[22] *Accord Behrendsen v. Yangtze River Port and Logistics Ltd.*, 2021 WL 2646353, *10 (E.D.N.Y. June 28, 2021); *Golesorkhi v. Green Mountain Coffee Roasters*, 973 F. Supp. 2d 541, 560 (D. Vt. 2013), *aff'd*, 569 F. App'x 43 (2d Cir. 2014). Even if the doctrine applied, it cannot be used to plead scienter. *In re Mylan N.V. Sec. Litig.*, 379 F. Supp. 3d 198, 213 (S.D.N.Y. 2019). The AC and Opposition are silent regarding what AZ's CFO knew or should have known about vaccine development.

Second, the AC lacks any non-conclusory allegations of Mr. Dunoyer's control as required for Section 20 liability. Mov. 35. The Opposition has no response, thus conceding the point.[23]

POINT III: PLAINTIFFS' BID TO IGNORE NINE DOCUMENTS FAILS

Plaintiffs assert that the Court should not consider nine documents submitted with Defendants' motion, as they "came into existence after the Class Period." Opp. 37 & Ex. D. But there is no rule against considering post-CP documents, particularly where securities plaintiffs challenge disclosures about clinical trials. Courts regularly look to what government regulators ultimately communicate in response to pending approval applications. *See In re Philip Morris Int'l Inc. Sec. Litig.*, 437 F. Supp. 3d 329, 344 n.3 (S.D.N.Y. 2020); *see also Kader v. Sarepta Therapeutics, Inc.*, 887 F.3d 48, 55 (1st Cir. 2018). Indeed, Plaintiffs ask this Court to consider post-CP documents and information. *See* ¶¶ 124-133; Ex. A. Plaintiffs cannot selectively define relevant post-CP information.

Moreover, the nine documents merely reiterate what the AC pleads or the Opposition already acknowledges, and none of the information for which the documents are cited is disputed. *See* Annex D. As such, and because the matters documented are judicially noticeable and integral to the AC (with Plaintiffs and investors having notice of them), this Court may consider them. *See Cortec Indus., Inc. v. Sum Holding L.P.*, 949 F.2d 42, 47-48 (2d Cir. 1991); *Rhee-Karn v. Burnett*, 2014 WL 4494126, *3 (S.D.N.Y. Sept. 12, 2014); *see also Gale v. Smith & Nephew, Inc.*, 989 F. Supp. 2d 243, 246 n.2 (S.D.N.Y. 2013) (public regulatory approvals are judicially noticeable); F.R.E. 201(b).[24]

CONCLUSION

For the above reasons, the AC should be dismissed. The dismissal should be with prejudice, as Plaintiffs neither identify how they would amend, Opp. n.38, nor provide any explanation for their

[23] As the AC fails to plead Mr. Dunoyer's scienter, it also pleads no culpable participation under Section 20. Mov. 35.

[24] *City of Austin Police Retirement System v. Krinkross Gold Corp.*, 957 F. Supp. 2d 277, 287 (S.D.N.Y. 2013), Opp. 37, refused to take judicial notice of the purported reason certain mining companies delayed projects in 2011, as it was a fact that would not have been well-publicized or generally known outside those companies.

failure to comply with Rule 3(D)(ii) of this Court's Individual Rules and Practices in Civil Cases.

Dated: New York, New York
February 4, 2022

Respectfully submitted,

FRESHFIELDS BRUCKHAUS DERINGER US LLP

/s/ Meredith Kotler

Meredith Kotler
Mary Eaton
Shannon McGovern
Adam M. Rosenfeld
601 Lexington Avenue, 31st Floor
New York, New York 10022
Telephone: (212) 277-4000
meredith.kotler@freshfields.com
mary.eaton@freshfields.com
shannon.mcgovern@freshfields.com
adam.rosenfeld@freshfields.com

Attorneys for Defendants